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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,425	07/03/2001	Roberto Valducci	242/9-1568	1890

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental **Office Action Summary**	Applicati n No. 09/898,425	Applicant(s) ROBERTO VALDUCCI	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This is a supplemental action in response to the telephone interview with attorney Sapone on 10/02/02. The amendment and remarks filed 07/08/02 and 08/21/02 are made of record and considered by examiner. Final rejection is withdrawn and claims 2-22 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 15, 18 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn as it relates to the trademark/trade name EUDRAGIT and preferably.

2. Claims 2-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is unclear. The phrase/clause starting after polymers in line 3 to dissolved, in line 6 is confusing.

Claim 2 is unclear. The phrase/clause starting after includes in line 2 and ending at pH 7 in line 4 is confusing.

Claims 3 and 22 are confusing because it is not clear what the symbols mean or represent. It is not clear what the "pH dependent ratios:" are in claims 3 and 22.

Claim 5 is indefinite because "including" in line 2 cannot be used after a recitation of "chosen" in line 1. Applicant may use proper Markush language where the active ingredient is chosen or selected from the group consisting of ---.

Claims 11 and 12 are confusing. Claim 12 appears to have more than two external layers

by the recitation of "one of the external layers" in line 2.

Regarding claims 15 and 18, the word "type" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "type"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

What are the L and M types as they relate to hydroxypropylmethylcellulosephthalate?

3. **The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.**

Other natters:

Claims 4 and 5 recite "such active ingredient" and it would be acceptable to recite either ---said active ingredient--- or ---the active ingredient---.

Claim 7 recites "such coating" and it would be acceptable to recite ---said coating--- or ---the coating---.

"Such mixture" in claim 18, "such polymer" in claims 15 and 19 could be ---said/the mixture--- and ---said/the polymer---.

Claim Rejections - 35 USC § 102

4. The rejection of claims 2-6, 8, 15, 18, 19 and 21 rejected under 35 U.S.C. 102(e) as being anticipated by Watts (US 6,228,396) is with drawn because of the persuasive argument presented in the response filed 07/08/02. Thus, the argument presented against the use of Watts is moot.

5. Claims 2, 3, 6, 8, 15, 16, 18, 19 and 21 remain rejected under 35 U.S.C. 102(e) as being anticipated by Yajima et al. (US 5,972,373).

Applicant agues that Yajima does not anticipate the claims because teaches compositions comprising high polymers, monoglycerides and unpleasant tasting drugs. Applicants also ague that Yajima does not teach multiphasic release by combining portions of an active ingredient with different polymers or mixtures of polymers which dissolve at different pH's so as to achieve drug delivery in different portions of the stomach.

6. Applicant's arguments filed 07/08/02 have been fully considered but they are not persuasive.

Applicant broadly claims an oral formulation that comprises an active agent combined with different polymers or mixtures of polymers where each polymer is soluble at starting pH's. The prior art only has to teach the composition. The claim is broadly to polymers and the recited property is inherent in the polymers of the prior art. The claims do not recite high or low molecular weight polymers and specific polymers are not recited that would have the property that applicant agues for. Any active agent in combination with any polymer(s) meets the limitation of the claims. The prior art of record teaches active agents in combination with polymers.

Yajima teaches a composition comprising macrolide antibiotics (column 2, lines 38-48) and polymers (column 2, lines 55-57). The composition is formulated into granules, powders, capsules, tablets and dry syrups (column 3, lines 15-18) and these formulations are enteric coated (column 3, line 48). The composition further comprises excipients (mannitol, carboxymethylcellulose), disintegrants (starch and crystalline cellulolse), binders (hydroxypropylmethyl cellulose and propyleneglycol alginate), lubricants (stearic acid) and antioxidant (BHT, BHA and alpha-tocopherol and citric acid). See column 3, lines 1-48). The

coating agent includes hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate and the composition further comprises dyestuff and titanium oxide (column 3, lines 58 and 59). Claims are broadly directed to active agents and polymer and a composition meeting the limitations of claim 1 would have the release profile recited in claim 3.

7. Claims 2, 5, 6-10, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kjorn es et al. (US 4,713,248).

Kjorn es teaches a controlled release multiple unit formulation comprising active agents coated with inner and optional outer film layers (column 2, lines 38-60). The formulation is in the form of capsules, sachets or tablets (column 6, lines 20-40). The inner film layer is a film-forming agent selected from carboxymethylcellulose and hydroxypropylmethyl cellulose, to name a few of the polymers listed in column 3, lines 46-59. The outer film layer is a film-forming agent and examples are hydroxypropylmethylcellulosephthalate, celluloseacetatephthalate, polyvinylacetatephthalate or mixtures thereof (column 5, lines 13-33). Kjorn es further teaches that the formulation may comprise of mixtures of diffusion coated and uncoated units where the active agents are the same or different (column 6, lines 30-41); EUDRAGIT is an example of diffusion coating materials in Kjorn es (column 8, lines 39-44). Active substances including substances having pH independent and pH dependent solubilities are listed in column 7, line 20 to column 8 line 27. Kjorn es anticipates the claims.

8. Claims 2-4, 6, 7, 10, 13-15, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al. (US 5,482,718).

Shah teaches a multiplayer tablet comprising a core, erodible polymer layer and an enteric coating layer (abstract). The core comprises 5-aminosalicylic acids, which is mesalazine

(see Sandborn et al, US 5,889,028, column 8, lines 19-24 for teaching of mesalazine as 5-ASA), microcrystalline cellulose, polyvinylpyrrolidone, magnesium stearate, mannitol and croscarmellose (example II). The erodible polymer layer comprises hydroxypropylmethylcellulose, microcrystalline cellulose, polyvinylpyrrolidone and magnesium cellulose; and the enteric coating layer comprises hydroxypropyl methylcellulose phthalate (example II). Shah anticipates the claims.

Claim Rejections - 35 USC § 103

9. The rejection of claims 2-16 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over Watts (US 6,228,396) in view of Ishizuka et al. (US 6,160,017) or Ishizuka et al. (US 6,160,017) in view of Watts (US 6,228,396) is withdrawn in light of the arguments presented on 0708/02.

10. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US 5,482,718).

Shah clearly teaches the formulation of the application except that Shah is silent on the different types of hydroxypropyl methylcellulose phthalate. But since Shah is silent on the types of hydroxypropyl methylcellulose phthalate, Shah teaches all the types of hydroxypropyl methylcellulose phthalate. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the multi-layer tablet formulation of Shah using all the type of hydroxypropyl methylcellulose phthalate because Shah teaches all types.

Regarding claim 20, Shah teaches 40 mg of 5-aminosalicylic acids and the 100-3000 mg of 5-aminosalicylic acids in the claim represents optimization of the amount of the active ingredient that would be delivered to the colon upon dissolution of the tablet.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
October 4, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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